served and the difficulty for this reviewer is to understand how this contract is to be developed. By and large, it must be through the individual - to do otherwise must be, as Hamilton points out, to change the medical ethic. Several of the participants share these doubts. Dr McWhinney, for example, points out that we must not make too much of a distinction between clinical and population competency for the latter will be applied through the former. Put another way by Sir Douglas Black: 'The ideal curriculum should recognise that population problems are aggregations of individual problems'. Moreover, while doctors must know about and understand the effect of the environment, both natural and manmade, on the distribution of ill-health, the resolution of such problems is not within the power of the medical school whose essential function, as Inui puts it, is to educate physicians.

How we are educating them is another matter. It may well be that the 'humanitarian dimensions' of doctoring are being sacrificed to the rote of science and it is certain that the undergraduate medical curriculum is too crowded. Perhaps we should avoid the concept of the five or sixyear undergraduate training programme and think more in terms of a ten-year graduate curriculum. In any event, the sweeping re-orientation suggested throughout the book is probably unattainable. The major difficulty is that the majority of, at least UK, hospitals are not community-based and the graduates go out to serve disparate populations - not excluding those of developing countries whose needs may be completely different. The paper by Marmot and Zwi, 'A model exercise in public health', demonstrates this only too well. Several contributors come from medical schools which claim that population-based education of the type envisaged can be achieved - but one suspects that Newcastle, NSW, for example, is, by reason of geography, the classic community-based medical school. In fact, the contributions from discussants are, in many ways, more readable than the primary papers insofar as they bring us back from Utopia to Camberwell.

This is a very seriously written book which is, incidentally, beautifully edited and well produced. In so far as medical ethics are founded in the medical school, it has an interest for readers of this journal - but it takes a long time to make a relatively narrow point. It is essentially for educationists and community physicians who will follow the discussions with interest and benefit.

> J K MASON Professor (Emeritus) of Forensic Medicine, University of Edinburgh

## International ethical guidelines for biomedical research involving human subjects

Council for International Organisations of Medical Sciences (CIOMS) and the World Health Organisation (WHO), 63 pages, Geneva, 1993, CIOMS, Swfr 10

These guidelines from the Council for International Organisations of Medical Sciences (CIOMS) and the World Health Organisation (WHO) are 'designed to be of use, particularly to developing countries, in defining national policies on the ethics of biomedical research, applying ethical standards in local circumstances, and establishing or redefining adequate mechanisms for ethical review of research involving human subjects'. It is an indication of how far agreement has been reached in principle about the important ethical issues to be addressed in medical research on humans that the guidelines given in this document do not differ, substantially, from most other recognised guidelines.

The CIOMS guidelines are a revised version of a 1982 draft. They have been updated because great changes have taken place both in the practice of biomedical research and in moral attitudes towards it. There has been a shift away from a duty-based morality in which a doctor is required to make decisions on his or her patient's behalf (and hence a researcher on his or her subject's behalf) towards acknowledging the autonomy of the individual. Further, the utilitarian pursuit of improving medicine for all has been checked by concern for those who would be the guinea pigs or subjects of research. These guidelines, then, give special attention to 'vulnerable groups', for example, children, pregnant lactating women, prisoners, people with HIV/AIDS or similar life-threatening diseases, and populations in underdeveloped countries which could be exploited.

The guidelines fully acknowledge the importance of respecting the autonomy of individuals, to the point where in guideline six the 'mentally and behaviourally disturbed' potential subject should be given a kind of partial autonomy - 'consent ... [should be obtained] to the extent of that subject's capabilities', and for children in guideline five it is suggested that at 13 they can understand enough to give consent. However, the guidelines also take seriously the need to protect subjects from harm, and seek always to balance non-maleficence and autonomy. While such a balance is never easy to strike, the guideline which succeeds best in this is number 15: 'Externally sponsored research'. Here the moral responsibilities of sponsors of research are spelled out. Research should not take place in underdeveloped countries just because requirements are not stringent there in the way they are in more developed countries. Rather, the research should take place as a response to local needs. The guideline stipulates that research protocols should be subjected to ethical review both in the sponsor's country and in the host country. (The logistics of this are interesting - does this mean Western countries should special, national research ethics committees created for this purpose?) External sponsors also, however, have an obligation to 'help develop the host country's capacity to carry out similar projects independently, research including their ethical review'. The sponsors should therefore employ local people to help with the research and should give money and advice to governments to set up local research ethics committees. The balance is struck between sponsors taking full responsibility for the research they undertake and in avoiding harm to its recipients, while at the same time enabling host countries to become self-sufficient in respect of ethical review and scientific expertise, so that they can decide for themselves.

These guidelines are extremely helpful. They present a basis for any country in the world to proceed with medical research. Their focus is almost entirely upon the protection of those who would be research subjects which, while this may be seen as a

limitation, does mean that underdeveloped countries are thereby protected from exploitation by external sponsors of research. Moreover, all who would engage in research on humans are reminded of the ethical obligations they then take on towards their research subjects.

> CLAIRE GILBERT FOSTER Sanofi Winthrop Research Fellow, Centre of Medical Law and Ethics, King's College, London

## Health care need

Per-Erik Liss, 141 pages, Aldershot, Hants, 1993, Avebury, £29.90

The debate about rationing health care is often conducted in a way that assumes we are able to measure the health care needs of groups and individuals. As this book makes clear, we are only just starting to develop a framework within which to measure health needs, predict the outcomes of treatments and define the conflicting priorities that influence resource allocation. This book is the attempt of a philosopher to organise our thinking about these complex issues.

Health care need is a revised version of a doctoral thesis published by Linköping University. It sets out to explore one frequently suggested criterion for allocating resources for health care. In many countries the link between resources and need is not explicit, but in Sweden the Public Health Act lays down that the policies of the health care system should be determined only by the needs of patients. The book draws on a wide range of work across Europe, the United Kingdom and North America.

The book follows a logical progression. It looks at the use of health care indicators and points out that indicators of less than perfect health do not establish a need. Neither does the established use of services indicate a need. Three possible definitions of health need are discussed: the supply notion, in which a health need depends on the existence of a suitable treatment; the normative notion, which states that the existence of a health care need is a matter of opinion; and the instrumental notion, which defines health need in terms of the availability of equipment and facilities within the health care system. These definitions are closely argued and lead on to further chapters discussing the concept of need, concepts of ill health, and ranking health care needs.

The closing section of the book suggests a model for assessing health care. Need assessment should involve establishing the actual health state of individuals, setting the goals of health care, and determining whether there is a treatment that will bring about a transition between the actual state and the goal. Health needs, defined in this way, are linked to helping people reach their own goals – the things that will make them happy.

Health care goals may be chosen, and it is the making of these choices that brings health care needs into existence. Defining these goals within society requires the involvement of professionals and citizens within representative bodies, whether these are democratically elected or health authorities.

The book does not reach the practical level of tackling the problems faced by health service researchers, clinicians or managers in defining needs, allocating resources or making choices between individuals. These are areas that remain complicated and difficult to work in. Many people are already working in the discrete areas discussed, although some applied research could benefit from the clarity of thought in developing an ordered approach to the subject. Initiatives such as the NHS Research and Development Strategy have supported the concept of identifying effective treatments, but are less clear about criteria for allocating resources to support these treatments.

The book does not give a list of easy answers. Clinicians and managers alike will struggle with it. However, it will provide a challenge to those who read it.

ANDREW FARMER
Health Services Research Unit,
Department of Public Health and
Primary Care,
Oxford University, Radcliffe Infirmary,
Oxford OX2 6HE

## Brain dead, brain absent, brain donors: human subjects or human objects?

Peter McCullagh, 261 pages, Chichester, 1993, John Wiley & Sons, £34.95 Replacement therapy is now well established as the preferred treatment for several hitherto fatal conditions and severe chronic diseases. However, transplant surgery is available to only a minority of likely beneficiaries. In countries where effective programmes exist the shortfall in the supply of organs and tissues suitable for successful replacement is a serious limitation. This book addresses the ethical issues pertaining to the use of those about to die or who are doomed to a futile existence as sources for much needed species-specific organs or in optimal physiological tissues condition. Utilisation of these sources requires medical interventions of a non-therapeutic nature which threaten to degrade the human individual from subject to object.

As stated by the title, the author's chief concern is with the application in this context of present-day concepts of brain death and of so-called brain absence. The historical approach is well suited to this purpose and he succeeds in presenting information and opinion with clarity and objectivity. I recommend the book to policy-makers concerned with the harvesting of human transplant material, to the workers that do it and to potential donors or recipients.

McCullagh has avoided undue use of medical, legal and philosophical jargon and succeeds in steering the reader through some deep and turbulent waters. He is rightly critical of the misleading and often inaccurate information issuing from so-called experts which is published in the news media and he gives some good examples of the obfuscations and gyrations performed by self-interested persons and groups. He accepts that the value of certain replacement therapy is sufficient to force re-appraisal of previously held attitudes and practices about death and the sanctity of human organs, but he has no patience with exponents of innovative treatments whose claim to human (fetal or neonatal) 'cadaveric' material is based on frail but widely publicized evidence of efficacy.

Without the contribution from 'brainless' individuals there would be little progress in replacement therapy and many patients would have to endure potentially treatable suffering. Peter McCullagh has set out in impressive fashion and in appropriate detail the ethical implications of the rush to procure tissues and organs from donors who have beating hearts but who are not 'brain living'.